UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/361,829 | 07/27/99 | HEATH | E 1074.003US1 |

027073 HM12/0404
FOGG SLIFER & POLGLAZE, P.A.
P.O. BOX 581009
MINNEAPOLIS MN 55458-1009

| EXAMINER | |
|---|---|
| LUNDGREN, J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1631 | 8 |

**DATE MAILED:** 04/04/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/361,829 | HEATH ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey Lundgren | 1631 | |

*-- The MAILING DATE of this communication app ars on th cover sheet with the correspondenc address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group I (claims 1-19) in the paper received on January 8, 2000 (Paper No. 6) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 20-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

### *Claim Rejections - 35 USC § 103*

3. The rejection of claims 1-7, 9-10, and 14-18, are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. (U.S. Patent No 5,773,221, June 30, 1998) in view of Stephens et al. (U.S. Patent No. 5,856,133, January 5, 1999) in view of Dionne et al. (U.S. Patent No. 5,800, 828, September 1, 1998) in view of Bacus et al. (U.S. Patent No. 4,175,860, November 27, 1979), in the Office Action mailed October 4, 2000, is withdrawn because the disclosure of Stephens does not disclose the aspiration of nucleic acids, but the aspiration of proteins.

4. The rejections of claims 8, 11-13, and 19, under 35 U.S.C. 103(a) as being unpatentable over Carlson et al., in view of Stephens et al., in view of Dionne et al., in view of Bacus et al., as applied to claims 7 above, and further in view of Thrush, McNutt, Poulter, and/or Johnson, are withdrawn for the previously mentioned reasons.

### New Grounds of Rejection

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-7, 9-10, and 14-18, are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. (U.S. Patent No 5,773,221, June 30, 1998) in view of Kelley et al. (U.S. Patent No. 5,679,154, October 21, 1997), in view of Vogel et al. (U.S. Patent No. 5,922,320, July 13, 1999), in view of Pfost et al. (U.S. Patent No. 5,369,566, November 29, 1994), in view of Bacus et al. (U.S. Patent No. 4,175,860, November 27, 1979).

The claims are drawn to a computer readable media for controlling the operation of an automated machine for isolating a nucleic acids from a sample, wherein commands for centrifugation, aspiration, mixing, and dispensing sub-module, wherein a command series is executed for a method for the isolation of DNA, wherein repeated centrifugation, mixing and aspiration/dispensing steps are performed.

Carlson et al., disclose a method of isolating DNA, wherein added reagents are mixed with a sample, centrifuged at a predetermined g-force for a predetermined time,

removing certain reagents, adding more reagents, and further centrifugation steps as necessary for DNA isolation DNA (see column 14:60 to column15:45).

Carlson does not specifically teach aspiration means for adding or removing various reagents and/or other liquids, nor does Carlson address the disclosed method in automated format.

Kelley discloses an automated centrifuge apparatus, wherein fluid is serially removed and added by aspiration with a pipette following and preceding centrifugation (see column 10:46-64).

Vogel discloses manipulating/transferring nucleic acids by aspiration for the advantages of not shearing the hybridized (column 25:26-37).

Pfost discloses a method of programming a controller in a manner by which a variety of menus, options, or questions for input parameters are presented to the user, for execution of a desired protocol on the mechanical means for performing automated laboratory equipment, such as for aspirating and transferring liquids in a controlled manner (see *Summary of the Invention*).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an automated aspiration/centrifugation system to perform the DNA isolation protocol of Carlson for adding, removing, and mixing samples, because Kelley teaches the advantages of an automated laboratory procedures/systems for isolating and manipulating biological materials, and because of the universally accepted advantages that automation provides, such as high throughput, reduced cost, reduced personnel, improved accuracy, and improved reproducibility as taught by Bacus (see Bacus, column 1:31-39 ; M.P.E.P. § 2144.04(III))[1]. One would have recognized that in handling nucleic acids, that shear forces can damage the nucleic acid sample, and that by handling the sample through gentle aspiration means, sample integrity can be maintained as disclosed by Vogel. Furthermore, the ordinary artisan would have been motivated to utilize software implementation for controlling system hardware, such as controllers, with graphical displays, as a means of providing

an interface with the user that is easy to operate for executing the desired automated laboratory procedures. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson, Kelley, Vogel, Pfost, and Bacus as applied to claims 1-7, 9-10, and 14-18 above, and further in view of Thrush (U.S. Patent No. 5,692,144, November 25, 1997).

Claim 8 is drawn to the computer system of claim 6, wherein a graphical user interface (GUI) is provided for user control of said computer system in executed the user-defined method.

Neither Carlson, Kelley, Vogel, Pfost, or Bacus specifically disclose the use of a GUI software interface.

Thrush teaches that GUIs are advantageous software interfaces for computer systems because human error is minimized and the software provides a "user-friendly environment" (see column 1, lines 29-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a GUI for communicating commands and results between the user and system, with the system of Carlson, Kelley, Vogel, Pfost, and Bacus, because Thrush teaches that GUIs provide a user-friendly environment and minimize human errors for system that communicate commands and results. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

9. Claims 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson, Kelley, Vogel, Pfost, and Bacus as applied to claims 1-7, 9-10, and 14-18 above, and further in view of Johnson et al. (U.S. Patent No. 5,584,039, December 10, 1996)

Claims 11 and 19 are drawn to computer means, wherein a dedicated processor is implemented.

---

[1] Automatic or mechanical means used to replace a manual activity which accomplishes the same result

Neither Carlson, Kelley, Vogel, Pfost, or Bacus, specifically teach the use of a dedicated processor.

Johnson summarizes the well-known advantages of using dedicating processors in computer systems wherein a processor is responsible for the control of multiple submodules and tasks as a means of more effectively distributing the work in a computer environment (see *Summary of the Invention*).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a dedicated processor with the computer module of Carlson, Kelley, Vogel, Pfost, and Bacus, because Johnson discloses the advantages of relieving the CPU's work load by means of a dedicated processor. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable Carlson, Kelley, Vogel, Pfost, and Bacus as applied to claims 1-7, 9-10, and 14-18 above, and further in view of Poulter et al. (U.S. Patent No. 6,072,795, June 6, 2000).

Claim 12 is drawn to the control module of claim 9 the use of computer systems with programs wherein said programs are burned into the processor with hard code.

Neither unpatentable Carlson, Kelley, Vogel, Pfost, or Bacus, specifically teach the use of computer systems with programs wherein said programs are burned into the processor with hard code.

Poulter discloses the use of computer systems with programs wherein said programs are burned into the processor with hard code for the advantages of reduce software programming (column 6, lines 8-19).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize computer systems with programs wherein said programs are burned into the processor with hard code with the computer module Carlson, Kelley, Vogel, Pfost, and Bacus, because Poulter teaches that said processor requires less

---

is not sufficient to distinguish over the prior art.

software support. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable Carlson, Kelley, Vogel, Pfost, and Bacus as applied to claims 1-7, 9-10, and 14-18 above, and further in view of McNutt (U.S. Patent No. 5,802,389, September 1, 1998)

Claim 13 is drawn to the control module of claim 9, wherein a programmable logic controller is implemented.

Neither Carlson, Kelley, Vogel, Pfost, or Bacus, specifically teach a control module wherein a programmable logic controller is implemented.

McNutt discloses that it is becoming increasingly important to provide programmable logic controllers (PLCs) which provide modular approaches. That is, the ability to enlarge a system by providing additional features and/or additional input/output analog and/or digital I/O. Modular systems allow for adaptation to simple and complex situations as well as increasing in cost in more manageable incremental steps. Further, due to the increased use of PLCs, it is now a de-facto requirement that such controllers be capable of being interconnected in a network type environment and being programmed and reprogrammed through a variety of means.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a PLC with the automated system of Carlson, Stephens, Dionne, and Bacus, because the well-known flexibility and modular nature that PLCs offer for automated systems as disclosed by McNutt. Therefore, the invention as a whole was *prima facie* obvious at the time the invention was made.

## ***Conclusion***

12. No claims are allowable.

13. Any inquiries concerning the *merits* of this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren, whose

telephone number is (703) 306-3221. The Examiner can normally be reached on Monday-Friday from 7:00 AM to 5:00 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Michael Woodward, can be reached at (703) 308-4426.

Any inquiries of a *general* nature relating to this application should be directed to Ms. Pauline Farrier, Patent Analyst for Art Unit 1631, whose telephone number is (703) 305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1631 using (703) 308-0294. Please notify the Examiner of incoming facsimiles prior to sending papers to the aforementioned fax number. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Jeffrey S. Lundgren, Ph.D.

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER